Ref.: SCBD/BS/CG/jh/69854 9 December 2009

NOTIFICATION

Invitation for Comments on the Draft Elements of a Strategic Plan of the Cartagena Protocol on Biosafety

Madam/Sir,

At its meeting on 8 November 2009, the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) requested that a process be initiated to enable Parties submit comments on the draft elements of a strategic plan (2011 to 2020) for the Cartagena Protocol on Biosafety prepared by the Secretariat. The draft is prepared based on submissions of Parties, information from national reports and relevant decisions of the COP-MOP, and also taking into account the elements and approach that are under consideration in the on-going revision of the Strategic Plan of the Convention.

The Bureau further directed that the draft elements of the strategic plan be submitted to Parties along with the report developed as regards methodological approach that is sought to contribute to an effective assessment and review of the Protocol as requested by the fourth meeting of the COP-MOP in paragraph 1 of decision BS-IV/15. It is hoped that the report may serve as a complementary document in helping Parties review the draft strategic plan and submit comments.

Further, the Bureau established the following schedule for consultations on the draft elements of the Strategic Plan for the Protocol.

December 2009 – January 2010:	Submission of draft elements of strategic plan and report on methods for the evaluation of the effectiveness of the Protocol to Parties (i.e. the present notification)
30 January 2010:	End date for the submission of comments for the initial consultation process by Parties

To: National Focal Points for the Convention on Biological Diversity (CBD-NFPs)

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February 2010:	Submission of updated draft elements of strategic plan to a discussion forum to be organized through the Biosafety Clearing-House for further comments;
March 2010:	Special segment of the COP-MOP Bureau meeting to consider the updated draft elements of the strategic plan and plan for further action

I, therefore, urge you to consult among national stakeholders and provide comments on the elements of the strategic plan attached as Annex I to the document accompanying this notification. The document is an evolving one which will eventually be submitted for the upcoming fifth meeting of the COP-MOP.

All comments during this phase of the consultation are expected to reach the Secretariat as soon as possible **but no later than 30th January 2010,** in order to enable the Secretariat update the draft elements of the strategic plan for submission to the discussion forum mentioned above in a timely manner.

Please accept, Madam/Sir, the assurances of my highest consideration.

Ahmed Djoghlaf
Executive Secretary

UNEP

CBD

DRAFT

Convention on Biological Diversity

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CONFERENCE OF THE PARTIES SERVING AS THE
MEETING OF THE PARTIES TO THE
CARTAGENA PROTOCOL ON BIOSAFETY
Fifth meeting
Nagoya, Japan, 11-15 October 2010
Item…of the provisional agenda*

ASSESSMENT AND REVIEW: STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY, 2011 - 2020

I. INTRODUCTION

1. The Cartagena Protocol on Biosafety requires, in Article 35, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) to undertake periodic evaluation of the effectiveness of the Protocol. The first evaluation of the effectiveness of the Protocol is reported in document UNEP/CBD/BS/COP-MOP/4/INF/14. In conjunction with this evaluation, COP-MOP decided, at its fourth meeting, to initiate a process towards developing a strategic plan for the Protocol. In this regard, Parties were invited to make submissions on a strategic plan for the Protocol and the Executive Secretary was requested to present a draft strategic plan for the consideration of COP-MOP at its fifth meeting (paragraph 2, decision BS-IV/15).

2. Accordingly, this document presents, in section II, background information on the existing elements of the strategic plan of the Convention on Biological Diversity (Annex, decision VI/26) that was related to the Protocol and its derived medium-term programme of work of the COP-MOP up to its fifth meeting. Section III highlights the main elements of a strategic plan for the Protocol submitted by Parties to the Protocol in accordance with the invitation of COP-MOP. Section IV of the document proposes some elements of a draft decision for consideration by COP-MOP.

3. Furthermore, the Secretariat has prepared, on the basis of the submissions and elements derived from the report of the evaluation of the Protocol, a draft strategic plan. As the period covered by the medium-term programme of work is due to end at the fifth meeting of the COP-MOP, the Secretariat has also prepared a draft programme of work for the period that the draft strategic plan is proposed to cover. Both the draft strategic plan and the proposed programme of work are made available as annexes to this document.

* UNEP/CBD/BS/COP-MOP/5/1

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II. BACKGROUND

4. A strategic plan of an organisation is a process that builds commitment from key stakeholders in a particular direction that guides the future allocation of resources. The process and areas that embody such a strategic plan are normally organization specific. A strategic plan also guides the development processes or implementation of institutional structures and procedures in achieving stakeholder derived targets.

5. The Conference of the Parties to the Convention on Biological Diversity adopted, at its sixth meeting, a strategic plan for the Convention. The development of the Strategic Plan had gone through different stages. A Workshop on the Strategic Plan was convened in Seychelles from 28 to 30 May 2001. The workshop resulted in conclusions which included elements for a vision, mission statement and operational goals of the possible strategic plan for the Convention. The strategic plan was also one of the items considered by an open-ended inter-sessional meeting which was convened from 19 to 21 November 2001 to assist with preparations for the sixth meeting of the Conference of the Parties. The inter-sessional meeting developed further the elements of the Strategic Plan including the issue, mission statement, vision, operational goals, constraints, monitoring and reporting and periodic assessment and review, review of implementation, and communication.

6. The Strategic Plan of the Convention (Annex, decision VI/26) comprises four goals. Each goal contains several objectives and one or more of these objectives were specific to the Protocol. The strategic objectives of the Protocol were set up as integral parts of the Strategic Plan of the Convention. For example, the first Goal of the Strategic Plan was to see the Convention fulfilling its leadership role in international biodiversity issues. One of the objectives set to be achieved in the pursuit towards this Goal was to realize that the Protocol was widely implemented. Similarly, goals two, three and four include objectives with regard to the Protocol. The following table consolidates the objectives identified in the Strategic Plan of the Convention that were specific to the Protocol and provides a preliminary review of progress towards achieving each of the objectives.

Goals	**Objectives specific to the Protocol**	**Progress**
1. The Convention is fulfilling its leadership role in international biodiversity issues	1.4 The Cartagena Protocol on Biosafety is widely implemented	• The Protocol entered into force in 2003, less than four years after its adoption; • At the time of finalizing this document 157 Parties to the Convention have ratified or acceded to the Protocol.
2. Parties have improved financial, human, scientific, technical, and technological capacity to implement the Convention.	2.3 Developing country Parties, in particular the least developed and the small island developing States amongst them, and other Parties with economies in transition, have increased resources and technology transfer available to implement the Cartagena Protocol on Biosafety.	• At least 120 countries have developed draft national biosafety frameworks documents and are in the process of operationalizing them
	2.4 All Parties have adequate capacity to implement the Cartagena Protocol on	More than 100 capacity-building projects have been

	Biosafety.	implemented by governments with support from different donor agencies and organizations Most developing countries have no or limited capacity to undertake risk assessment and to design and implement risk management schemes.
3. National biodiversity strategies and action plans and the integration of biodiversity concerns into relevant sectors serve as an effective framework for the implementation of the objectives of the Convention.	3.2 Every Party to the Cartagena Protocol on Biosafety has a regulatory framework in place and functioning to implement the Protocol	About 43 developing countries still lack any form or elements of a functional biosafety regulatory framework
4. There is a better understanding of the importance of biodiversity and of the Convention, and this has led to broader engagement across society in implementation.	4.2 Every Party to the Cartagena Protocol on Biosafety is promoting and facilitating public awareness, education and participation in support of the Protocol	According to the first national reports submitted to the Secretariat in 2007, 49 per cent of the Parties reported having promoted and facilitated public awareness, education and participation to a large extent to a significant extent and 47 per cent had done so to a limited extent.

7. The mission statement of the Strategic Plan of the Convention was a commitment by Parties to a more effective and coherent implementation of the three objectives of the Convention to achieve, by 2010, a significant reduction of the rate of biodiversity loss. As the 2010 biodiversity target is approaching, the Conference of the Parties decided, at its ninth meeting held in May 2008, on a process to revise the current Strategic Plan of the Convention and adopt a new one that envisions beyond the 2010 target. Accordingly, the Secretariat is preparing, on the basis of submissions from Parties and observers, a draft updated Strategic Plan with input from the Working Group on Review of Implementation of the Convention at its third meeting. The draft strategic plan for the Protocol presented as Annex 1 of this document has, therefore, been prepared taking into account the updating of the Strategic Plan of the Convention, including the analysis of issues considered in the updating process. The draft strategic plan of the Protocol is further designed to be coherent and consistent with the reviewed strategic plan of the Convention.\

8. It is noted that whilst the Convention has substantially developed its processes and institutions to support its objectives and is at the verge of its implementation phase, the processes and institution under Biosafety Protocol are still evolving and are being developed both at the international; and national levels.

9. III. SUBMISSIONS ON A STRATEGIC PLAN FOR THE PROTOCOL

10. In response to the invitation by the fourth meeting of COP-MOP and the Secretariat's follow up notification, the Governments of Japan, Norway, Thailand and the European Union made submissions of views on a strategic plan for the Protocol. Each submission is different in its structure and details. However, there is a great deal of convergence in the elements identified to be included in the strategic plan. For example, risk assessment and risk management and handling, transport, packaging and identification are elements that have been identified by all submissions invariably. Capacity building is another item of interest for most of the submissions. Liability and redress, cooperation with other organizations or processes, and information sharing are also items suggested to be addressed in the strategic plan. The full texts of the submissions are available in an information document (UNEP/CBD/BS/COP-MOP/5/INF/XX).

IV. ELEMENTS OF A DRAFT DECISION

11.

Annex 1

DRAFT STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY 2010-2020

THE CONTEXT

The Cartagena Protocol on Biosafety was adopted in January 2000 and entered into force on 11 September 2003. The first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) adopted, on the basis of recommendations from the Intergovernmental Committee on the Cartagena Protocol on Biosafety, a medium-term programme of work for the period covering from the second to the fifth meeting of the COP-MOP.

Over the past 6 years significant achievements have been made towards the implementation of the Protocol. The number of Parties has increased by more than 100 since the entry into force of the Protocol. The medium-term programme of work has made an immense contribution in guiding the work under the Protocol. Many decisions on tools, guidelines and mechanisms were adopted. The Biosafety Clearing House became fully operational. More than 100 countries received, through UNEP/GEF as an implementing agency of the Global Environment Facility (GEF) and other GEF implementing agencies, capacity building assistance in support of their efforts to develop and implement their national biosafety legal and administrative frameworks. The number of bilateral, sub-regional and regional cooperative arrangements to support biosafety capacity building activities has also increased significantly in the past years.

The medium term programme of work of the COP-MOP is due to end at the fifth meeting. A process has been established to undertake assessment and review of the effectiveness of the Protocol in accordance with Article 35 of the Protocol. The initiation of the assessment and review process on the one hand, and the completion of the medium-term programme of work on the other, presented opportunity for Parties to consider developing a long term vision in the form of a strategic plan and a corresponding multi-year programme of work. The opportunity has become even broader due to the on-going process to revise and update the Strategic Plan of the Convention in light of a new thinking and resolve for action beyond the 2010 biodiversity target.

Significant challenges remain as regards the implementation of the Protocol. Parties still need to provide more guidance and clarify procedures and processes in areas such as the application of the advance informed agreement procedure, compliance (Article 34), liability and redress (Article 27), risk assessment and risk management (Articles 15 and 16), handling, transport, packaging and identification (Article 18) or capacity-building (Article 22). One of the major prerequisites of a successful implementation of planned activities is the provision of sufficient financial resources including alternative mechanisms for funding and technical support especially for developing countries and countries with economies in transition.

This draft strategic plan and the work programme accompanying it (Annex II) have been prepared on the basis of the few submissions received by the Secretariat, the analysis of the first national reports, experience gained through the development, implementation, and currently, updating of the Strategic Plan of the Convention, and the successive decisions taken by the Conference of the Parties serving as the meeting of the Parties to the Protocol from the first to its fourth meetings.

Please refer to the Elements in the table attached.

MONITORING, REVIEW AND EVALUATION OF THE STRATEGIC PLAN;

This strategic plan will be implemented through a programme of work which, if necessary, be adjusted, from time to time, on the basis of experience gained in the implementation of the requirements of the Protocol, as well as the result of the periodic assessment and review of the effectiveness of the Protocol as provided in Article 35 of the Protocol. A mid-term evaluation will be undertaken five years after the adoption of the Strategic plan. This process will take into consideration national reports to be assessed against the indicators of each operational objective. The evaluation will capture the effectiveness of the Strategic Plan and allow Parties to adapt to emerging trends in the implementation of the Protocol.

Annex II

MULTI-YEAR PROGRAMME OF WORK OF THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY UP TO 2020

/…

1. Standing Items:

(a) Matters relating to the financial mechanism and resources;

(b) Report of the Executive Secretary on the administration of the Protocol;

(c) Programme of work and budget for the Secretariat as regards its costs of distinct secretariat services for the Protocol;

(d) Report of the Compliance Committee.

2. The Conference of the Parties serving as the meeting of the Parties to the Protocol may consider, inter alia, the following items:

2.1 Sixth meeting:

(a)

2.2 Seventh meeting

(a)

2.3 Eighth meeting

(a)

2.4 Ninth meeting

(a)

2.5 Tenth meeting

(a)

DRAFT ELEMENTS OF THE STRATEGIC PLAN DATE: 081209

CARTAGENA PROTOCOL ON BIOSAFETY

VISION

Biological diversity is adequately protected from any adverse effects of living modified organisms.

MISSION

To strengthen global action in ensuring the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Strategic Objective	***Expected Impacts***	***Operational Objectives***	***Outcomes***	***Indicators***
1. To put in place further tools necessary to make the Protocol fully operational	Full implementation of the Cartagena Protocol on Biosafety by Parties Enhanced performance by Parties towards the attainment of the overarching objectives of conservation and sustainable use of biological diversity	1.1 To further develop and produce science based tools on common approaches on risk assessment and risk management for Parties	• Guidance on risk assessment and risk management that addresses new developments in modern technology made available to Parties and other stakeholders • Common approaches on risk assessment and risk management established and adopted by Parties and other Governments, as appropriate	• Significant number of tools and guidance documents on risk assessment and risk management produced and provided to Parties and other Governments. • Significant number of Parties adopt common approaches to risk assessment and risk management • Potential adverse effects of LMOs to biodiversity minimized
		1.2 To ensure that Parties meet the requirements for identification of living modified organisms	• All shipments of living modified organisms intended for direct use as food, feed or for processing, contained use and intentional introduction into the environment, identified through accompanying documentation in accordance with the requirements of the Protocol and COP-MOP decisions	• Increasing number of Parties report on documentation requirements for living modified organisms intended for direct use as food or feed, or for processing in their second, third and fourth national reports • Increasing number of Parties report on documentation requirements for living modified organisms for contained use or intended for intentional introduction into the environment in their second, third and fourth national report
		1.3 To adopt and implement rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms	• International rules and procedures on liability and redress for damage resulting from the transboundary movements of living modified organisms, adopted, ratified by Parties and entered into force • Each Party takes administrative and legal measures necessary to implement, at the domestic level, the rules and procedures on liability and redress	• The adoption of the international rules and procedures on liability and redress for damage resulting from the transboundary movements of living modified organisms • The entry into force of the international rules and procedures on liability and redress prior to the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol • Increased number Parties having in place domestic administrative and legal frameworks incorporating rules and procedures on liability and redress for damage caused by living modified organisms in place

		1.4 To clarify the basic socio-economic factors that may be taken into account in reaching decisions on import of living modified organisms	• Appropriate guidelines regarding socio-economic considerations of living modified organisms developed, and used by Parties • Socio-economic considerations applied, where appropriate, by Parties in a manner that makes biosafety and international trade mutually supportive	• Number of Parties reporting on their positive experiences in taking into account socio-economic considerations in reaching decisions on import of living modified organisms
		1.5 To develop tools and guidance to assist Parties to implement the Protocol's provisions relating to transit and contained use, unintentional transboundary movements and emergency measures and public participation in decision making regarding living modified organisms.	• Parties equipped to respond to living modified organisms in transit through their territories • Guidance developed to assist Parties in detecting and notifying other States of the occurrence of unintentional releases of living modified organisms on their territories and determining appropriate action, including emergency response measures • Increased public participation in decision-making processes regarding living modified organisms	• Number of Parties using the guidance to detect occurrence of unintentional releases of living modified organisms and to take appropriate response measures. • The number and variety of tools, techniques and approaches to public participation made available to Parties.
2. To further develop and strengthen the capacity of Parties to implement the Protocol	Effective and efficient regulatory, administrative and information exchange systems established by Parties for the implementation of the Protocol More expeditious and transparent decision-making	2.1 To put in place effective mechanisms for developing, coordinating and monitoring capacity-building activities	• A more cohesive approach and an effective mechanism established for biosafety capacity-building • Improved understanding of the capacity building needs of developing country Parties and Parties with economies in transition • Parties have adequate and predictable financial and technical resources enabling them to implement their obligations under the Protocol in an integrated and sustainable manner • Adoption and implementation of comprehensive national capacity-building strategies and action plans by each Party	• All Parties have assessed their training and institutional capacity-building needs and submitted the information to the BCH by 2011 • At least 50% of the Parties have developed national capacity-building action plans for implementing the Protocol by 2012 • At least 50% of the Parties have put in place training programmes for personnel dealing with biosafety issues and for long-term training of biosafety professionals • Parties have in place national coordination mechanisms for biosafety capacity-building initiatives • Improved coordination and collaboration between Parties and entities implementing or funding biosafety capacity building efforts • Existing resources and opportunities leveraged and more effectively used • Existing regional and national networks and institutions collaborating more closely to advance capacity building in biosafety

	Parties are enabled to make scientifically sound risk assessments with any necessary strategies put in place Increased safety in the transboundary movement, handling and use of living modified organisms	2.2 To ensure that all Parties have operational national biosafety frameworks in place for the implementation of the Protocol	• Decisions regarding the safety of a living modified organism are based on well established regulatory and administrative rules • Biosafety issues and the implementation of the Biosafety Protocol are integrated into the other relevant sectors, in particular agriculture, environment/biological diversity, health and science and technology sectors	• All Parties have in place national biosafety policies and laws by 2015, including systems for inspection, monitoring and enforcement of such laws • The majority of the Parties effectively implementing their biosafety laws and regulations • All Parties have a national focal point and competent national authorities designated • All Parties have national biosafety committees or similar bodies in place • At least 50% of the Parties have in place clear administrative rules and procedures for handling notifications and requests for approval of imports or release of LMOs • All Parties have systems for the protection of confidential information
		2.3 To enable Parties to carry out risk assessments in a scientifically sound and transparent manner and to regulate, manage and control risks of LMOs	• Resources, including human resources required to assess and manage risks of living modified organisms are available at national, sub-regional or regional level • Infrastructure and administrative frameworks established for the assessment and management of risks of living modified organisms at national, sub-regional or regional level • Training materials and scientifically-sound technical guidance on risk assessment and risk management developed and being used by Parties	• Number of people successfully trained on risk assessment and risk management through face-to-face training events as well as through long-distance training • Number of risk assessment reports produced that are compatible with the Protocol
		2.4 To develop capacity for handling, transport, packaging and identification of living modified organisms	• Customs/border officials are enabled to enforce requirements related to handling, transport, packaging and identification of living modified organisms • Personnel are trained and equipped for sampling, detection and identification of LMOs	• Number of customs officers and laboratory personnel trained • Number of Parties reporting experience with the sampling of shipments and detection of LMOs in their second, third and fourth national reports

		2.5 To assist Parties to the Protocol in their efforts to apply the rules and procedures on liability and redress for damage resulting from the transboundary movements of living modified organisms	• An institutional mechanism or process identified or established to facilitate the implementation of the international rules and procedures on liability and redress at the national level.	• The number of Parties that received capacity building support through a bilateral or multilateral avenue in the area of liability and redress involving living modified organisms • The number domestic administrative or legal instruments amended or newly enacted taking into account the international rules and procedures on liability and redress
		2.6 To enhance capacity at the national, regional and international levels that would facilitate efforts to raise public awareness, and promote education and participation concerning the safe transfer, handling and use of LMOs	• Parties have access to guidance and training materials on public awareness, education and participation concerning the safe transfer, handling and use of LMOs • Parties are enabled to promote and facilitate public awareness, education and participation in biosafety	• All Parties will have in place national communication strategies on biosafety by 2012 • All Parties have in place national websites and searchable archives on biosafety • At least 50% have national resource centres or sections in existing national libraries dedicated to biosafety educational materials • All Parties to have in place by 2012 mechanisms for ensuring public participation in decision-making concerning LMOs • Support tools (e.g. templates, toolkits, etc.) developed and used by national focal points, educators and communicators on biosafety • Case studies and best practices in public awareness, education and participation concerning the safe transfer, handling and use of LMOs prepared and shared • A network of biosafety education and communication experts put in place by 2011
		2.7 To ensure that the BCH is easily accessed by all stakeholders, in particular in developing countries and countries with economies in transition	• Increased access and information sharing of developing countries and countries with economies in transition • Enhanced access to capacity-building information for implementation of the Cartagena Protocol • Enhanced support to the Coordination Mechanism for the Action Plan for Building Capacities for the Effective Implementation of the Protocol • Information is easily accessible to stakeholders including the general public • Tools to facilitate implementation of the Protocol are easily accessible	• Enhanced capacity to submit and retrieve information from the BCH • Increased number of submissions and traffic from developing countries and countries with economies in transition

3) To expand the reach of the Protocol and promote cooperation	Increased political support for the implementation of the Protocol	3.1 To achieve universal membership to the Protocol	• All Parties to the Convention on Biological Diversity become Parties to the Protocol • Global recognition of the Cartagena Protocol on Biosafety as the main instrument in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology; • Compliance with the Protocol is facilitated	• At least 50% of non-Parties become Parties within one year of adopting this Strategic Plan • All Parties to the Convention on Biological Diversity become Parties to the Protocol by 2015
	Increased support from and collaboration with relevant organizations, conventions and initiatives for the implementation of the Protocol	3.2 To enhance international cooperation and collaboration in biosafety	• Parties to the Protocol which are also parties or members to other relevant processes promote policies or positions that are consistent with the objective of the Protocol • Increased synergies between the implementation of the Protocol and other processes relevant to biosafety • Improved coordination and collaboration among Parties, relevant organizations and initiatives	• Marked increase in the rate of utilization of the services of and information provided by competent international organizations by Parties to the Protocol.
		3.3 To raise the profile of the Protocol	• Increased awareness and visibility of the Protocol • All Parties have designed and implemented education and communication strategies resulting increased awareness of biosafety issues and the safe use and handling of living modified organisms by the general public, in particular farmers • Biosafety issues and the Protocol relevant activities are regularly covered by local as well as international media • Biosafety introduced in relevant curricular of academic or training institutions	• The number of active national awareness programmes on biosafety • The number of national websites or databases on biosafety • The number and diversity of awareness and educational materials on biosafety and the Protocol available and accessible to the public in print and electronic formats, including through the BCH, national websites and other communication channels

4) To strengthen compliance with and effectiveness of the Protocol	Parties are in compliance with the requirements of the Protocol;	4.1 To strengthen the mechanisms that facilitate compliance	• Each Party regularly monitors the implementation of its obligations under the Protocol and submits complete and timely national reports • The Compliance Committee is able to thoroughly review the implementation of obligations by Parties and to propose appropriate measures • All Parties able to enforce their regulatory frameworks and decisions	• Parties identifying their general non compliance issues and addressing them • National regulatory frameworks working effectively
		4.2 To improve the effectiveness of the Protocol	• Assessment and review of the Protocol, including its procedures and annexes, are undertaken on a regular basis • The Protocol, including its procedures and annexes, is adapted by Parties to new developments in the field of modern biotechnology	• COP-MOP undertakes regular assessment and review reports • Number of Parties modifying their national biosafety frameworks with the aim of adapting to new challenges
5) To enhance the availability and exchange of relevant information through the Biosafety Clearing-House	Transparency in the development and use of LMOs; Informed decision making; Enhanced public awareness; Increased compliance with national requirements	5.1 To increase the amount and quality of information submitted to and retrieved from the BCH	• The BCH is recognized as the most authoritative repository of information on Biosafety • Information submitted to the BCH is accurate, complete and timely • A larger number of countries submit and retrieve information • Risk assessment reports are shared in a timely manner through the BCH • Facilitated access to resources and experiences related to biosafety	• Increased recognition and visibility for BCH and SCBD • Ratio of risk assessment reports as against number of decisions on LMOs • Increased number of publications contained in the Biosafety Information Resource Centre (BIRC) • Increased number of BCH visitors • Increased number of references to the BCH • Ability of stakeholders to recognize or recall the BCH brand and imag
		5.2 To establish the BCH as the most effective platform in assisting countries in the implementation of the Protocol	• Countries are better equipped with tools developed and made available through the BCH	• Increased preference by Parties and other stakeholders to use the BCH platform for discussions and conference • Increased number of online discussions and real-time conferences carried out through the BCH platform
			• The BCH principles of inclusiveness, transparency and equity are applied consistently	• Increased level of participation to BCH biosafety discussions, in particular from developing countries and countries with economies in transition • Facilitated Protocol discussions and negotiating processes organised through the online and real-time tools offered by the BCH

Assessment and Review under Article 35 of the Cartagena Protocol on Biosafety

Discussion Paper on a Proposed Framework for the Second Assessment and Review

I. Introduction

1. Article 35 of the Cartagena Protocol on Biosafety (CPB) requires the Conference of the Parties serving as the meeting of the Parties of the Cartagena Protocol (COP-MOP) to undertake, five years after the entry into force of the Protocol, and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

2. In accordance with the terms of Article 35, the first evaluation under Article 35 was due to be conducted in 2008. At its fourth meeting in May 2008, the COP-MOP had before it submissions from a number of Parties and governments,[1] as well as a document prepared by the Executive Secretary.[2] The COP-MOP adopted Decision BS-IV/15 on *Assessment and Review*. The Decision noted the limited experience gained by Parties in the implementation of the Protocol, as reflected in the first national reports, and recognised that the lack of operational experience did not provide a good basis for an effective assessment and review of the Protocol.

3. In its Decision BS-IV/15, the COP-MOP, *inter alia*, requested the Executive Secretary to (i) develop a sound methodological approach to contribute to an effective second assessment and review of the Protocol, its annexes, procedures and mechanisms, on the basis of the information contained in the first national reports, answers to the "effectiveness questionnaire", the reports of the Compliance Committee, information on the Biosafety Clearing-House and any other relevant documents; and (ii) draft criteria or indicators that could apply in the evaluation of the effectiveness of the Protocol and provide an indication of the utility. This paper is intended to contribute to the response to that request, by setting out suggestions for the methodology for the second evaluation of effectiveness under Article 35 of the Cartagena Protocol on Biosafety.

4. Decision BS-IV/15 also invited Parties to make submissions on a strategic plan for the Protocol, and requested the Executive Secretary to present a draft strategic plan for consideration at COP-MOP 5. Work on preparation of a strategic plan for the Protocol has been initiated by the Secretariat (SCBD) and is ongoing.

5. The paper has been prepared through a desk study.[3] It should be stressed that no attempt is made in this paper to conduct the evaluation of the effectiveness of

[1] UNEP/CBD/BS/COP-MOP/4/INF/10.
[2] UNEP/CBD/BS/COP-MOP/4/14.
[3] The desk study comprised review and analysis of a variety of material, including: the text of the CPB and relevant COP-MOP decisions; the SCBD's analyses of information contained in the first national

the Protocol or to prejudge the outcome of such an evaluation. Nor does the paper seek to establish a baseline of the status of implementation of the Protocol against which future evaluations might measure. Rather the paper seeks solely to consider a possible methodology for the conduct of the second assessment and review.

6. While Article 35 requires periodic evaluations of the effectiveness of the Protocol, it does not provide guidance as to how such evaluations should be conducted. Nor does it specify the nature or scope of the evaluation beyond indicating that it should encompass an assessment of the Protocol's procedures and annexes. There are a number of generic challenges associated with designing and conducting an evaluation of the effectiveness of a multilateral environmental agreement. As Raustiala has highlighted, in a study conducted for UNEP in 2001, '[e]ffectiveness is a concept that can be defined in various ways: as the degree to which a given rule induces changes in behaviour that further the goals of the rule; the degree to which a rules improves the state of the underlying problem; or the degree to which a rule achieves it inherent policy objectives.'[4]

7. There are a number of approaches that might be taken to reviewing the effectiveness of the CPB. The review might focus on the degree to which the Protocol's provisions have been implemented by Parties; it might examine the establishment and functioning of procedures and mechanisms at both the national and international level envisaged in the Protocol; and/or it might examine the extent to which the adoption and implementation of the Protocol has contributed to the achievement of the overall objective of the Protocol. The review might also be directed towards assessment of the adequacy and scope of the Protocol's procedures and annexes in light of evolving scientific and technical knowledge about any risks that may be posed to biological diversity by living modified organisms, taking into account risks to human health.[5]

8. Part V of this paper considers in more detail the possible focus and scope of the second evaluation of effectiveness of the CPB. In general terms, it is submitted that, for the reasons highlighted in Part V below, the second evaluation of effectiveness should focus primarily on ascertaining the overall level of domestic implementation of the Protocol: i.e. the extent to which the Protocol has led to date to establishment and operation of functioning domestic regulatory systems for biosafety. It is also acknowledged that the focus of the

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reports; the reports of the Compliance Committee and documentation prepared for Compliance Committee meetings; submissions by Parties on Article 35 made prior to COP-MOP 4; documentation relating to the CPB's capacity-building Coordination Mechanism, including reports of meetings of the Liaison Group on Capacity-Building for Biosafety; documentation on the Convention on Biological Diversity Strategic Plan and the Biodiversity Indicators Partnership; a survey of the range of information available on the Biosafety Clearing House; general literature on the effectiveness of multilateral environmental agreements (MEAs); and documentation relating to effectiveness evaluation and strategic plans under other MEAs.

[4] K. Raustiala, *Reporting and Review Institutions in 10 Multilateral Environmental Agreements*, UNEP 2001, at 6.

[5] UNEP/CBD/BS/COP-MOP/3/13, 9 January 2006, *Initiating a process of evaluation of the effectiveness of the Protocol*, para. 5. See also, CPB, Articles 7(4) and 16(5).

evaluation of effectiveness might change over time as subsequent Article 35 assessments are conducted.

9. The paper is structured as follows: Part II briefly reviews progress in implementation of the Protocol since its entry into force in 2003; Part III highlights approaches to effectiveness evaluation taken in certain other multilateral environmental agreements; Part IV refers to developments in relation to the Strategic Plan of the Convention on Biological Diversity; and Part V addresses considerations relating to the scope of the second evaluation of effectiveness under Article 35 of the CPB. Part VI sets out suggestions for the possible methodology for the conduct of the second evaluation of effectiveness, and makes some brief observations on possible steps towards future evaluations of effectiveness of the CPB. Finally Part VII summarises conclusions and recommendations. The Annex to the paper sets out a number of draft indicators for consideration as the basis for the second evaluation of effectiveness.

II. Progress in implementation of the Protocol since entry into force

10. The Cartagena Protocol entered into force on 11 September 2003, and in November 2009 had 156 Parties.[6] The Protocol's objective, stated in Article 1, is:

> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Domestic implementation by Parties

11. The Protocol relies principally for its effective implementation on the domestic implementation by Parties of procedures to regulate, *inter alia*, the transboundary movement of living modified organisms (LMOs) for intentional release into the environment and of living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs).

12. It was apparent at the time of the Protocol's adoption that while some Parties had in place existing relevant domestic regulatory procedures, there would be many Parties that were not immediately in a position to implement the Protocol's central regulatory mechanism, the advance informed agreement procedure. Thus, even before the Protocol entered into force mechanisms were established to promote the further development of capacity at the domestic level for implementation of the Protocol's procedures. In particular, many eligible countries have received support through the Global Environmental Facility to develop national biosafety frameworks (NBFs).

[6] In addition, Bosnia and Herzegovina's accession to the CPB will take effect from 30 December 2009.

13. By July 2009, 110 countries had finalised their NBFs under the UNEP-GEF project.[7] Nonetheless, it is evident that a state that has completed the NBF process is not necessarily in a position to implement the Protocol in terms, for example, of dealing with an application for the first import of an LMO for intentional introduction into the environment. In some cases, while draft legislation may have been prepared, it has not been enacted;[8] and in others secondary regulations that form an integral component of an operational regulatory system have not been finalised and adopted. In numerous cases, it is suggested, even though a regulatory framework has been put in place, Parties may not be in a position to process an application due to a lack of sufficient technical or other capacity. The Capacity-Building Action Plan adopted by the COP-MOP is designed to address the capacity-deficit that still hampers full implementation of the Protocol.[9] This is discussed in paragraph 23 below.

14. Notwithstanding the significant activity and effort that has been devoted to the Protocol's implementation since its adoption, there remain gaps and deficiencies in implementation. The SCBD's 2008 revised analysis of information contained in national reports noted that in most regions significant gaps were acknowledged regarding the introduction of necessary legal, administrative and other measures required to implement the Protocol.[10] In particular, the revised analysis of information in national reports concluded that implementation of the AIA procedure was generally low and that the full application of the procedure had not yet been fully realised.[11] It also noted that the slow pace of implementation of requirements relating to Article 18 remained of utmost concern to parties of import of LMOs.[12] A number of countries, it was noted, had not yet provided information to the Biosafety Clearing House as required under Article 20 of the Protocol, again in many cases reportedly due to the fact that draft legislation contained in NBFs had not yet been implemented or applied in practice.[13]

15. In its review of general issues of compliance, on the basis of the analysis of national reports, the Compliance Committee has noted the continued existence of significant gaps in relation to the obligation to put in place at the national level the necessary legal, administrative and other measures. The Committee has further noted that compliance with the obligation to promote public awareness and participation is not at a satisfactory level. It has also identified gaps with respect to implementing the requirement to adopt national measures addressing illegal transboundary movements of LMOs and reporting such occurrences to the BCH.[14]

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[7] http://www.unep.org/biosafety/.
[8] A search for national laws and regulations on the BCH reveals that a number of NBFs remain on the BCH in draft form.
[9] Decision BS-I/5; Decision BS-III/3; Decision BS-IV/3.
[10] UNEP/CBD/BS/CC/5/2, para. 21.
[11] *Ibid*, para. 98.
[12] *Ibid.*
[13] *Ibid.*
[14] UNEP, CBD/BS/COP-MOP/4/2, *Report of the Compliance Committee*, 5 December 2007, paras. 16-18. UNEP/CBD/BS/CC/5/4, *Report of the Compliance Committee under the CPB on the Work of its Fifth Meeting*, 21 November 2008, para. 19

16. As discussed further in Part V below, the status of implementation of the Protocol, and gaps in knowledge about the extent to which it is implemented in Parties, have implications for the consideration of the scope of the effectiveness evaluation under Article 35.

Action taken by the COP-MOP

17. The Protocol directed or enabled a number of additional steps to be taken by the COP-MOP after the Protocol's entry into force to 'complete' the regime established in the Protocol and its institutional mechanisms. These included the establishment of compliance procedures and mechanisms (Article 34); the consideration of the modalities of the Biosafety Clearing House established by Article 20 of the Protocol; the consideration of rules and procedures on liability and redress (Article 27); and the consideration of further rules under Article 18(2)(a) on documentation accompanying LMO-FFPs subject to transboundary movement. Over its first four meetings, the COP-MOP has made progress on each of these issues, and on other aspects related to the elaboration of common understandings and guidance relating to the Protocol's provisions.

18. In terms of institutional arrangements, the compliance procedures and mechanisms were addressed at COP-MOP 1, and a Compliance Committee established.[15] The Committee has met regularly and is functioning, but it has yet to receive any admissible communications relating to instances of possible non-compliance with the Protocol.[16] This is surprising given that it is generally acknowledged that many Parties are not yet in a position to implement the Protocol fully.

19. In terms of mechanisms for information-sharing, the Biosafety Clearing House has been established and is operational.[17] Much work has gone in to developing the BCH as an accessible and functional tool. The Protocol's procedures for LMOs and LMO-FFPs rely significantly on the BCH as an effective information-sharing mechanism. Nonetheless, it has been noted that there remain some significant gaps in the information available through the BCH and some operational difficulties remain, particularly in terms of the apparently limited notifications made to the BCH to date.[18] It is striking, for example, that a search for 'decisions on LMOs for intentional introduction into the environment', including AIA decisions, on the BCH reveals that only 13 Parties, and four non-Parties, appear to have notified such decisions through the BCH. For LMO-FFPs, decisions can be found on the BCH for 17 Parties, and four non-Parties.[19] This appears to suggest either that such decisions are not being made by many Parties, or that they are being made but are not being notified through the BCH. The SCBD produced a summary of records available through

[15] Decision BS-I/7.
[16] UNEP/CBD/BS/COP-MOP/4/2, 5 December 2007, para. 21; UNEP/CBD/BS/CC/5/4, 21 November 2008, paras. 24-25.
[17] Decision BS-I/3.
[18] One analysis of impediments to the provision of information to the BCH is contained in A. Gupta, *Effective Participation in the Biosafety Clearing House: Participation Options and impediments to information provisions*, An academic report prepared for the UNEP-GEF BCH Project, May 2008, at 18-24. See also UNEP/CBD/BS/CC/6/3, 30 September 2009, para.7.
[19] As at November 2009.

the BCH, as required by the CPB, for the sixth meeting of the Compliance Committee in 2009. The report notes that while there has been a general increase in the amount of information reported to the BCH over the years for all the main categories of data, there still remain important gaps.[20] The ongoing development of the BCH is informed by the BCH Informal Advisory Committee established pursuant to Decision BS-I/3.

20. The national reporting cycle has commenced, with first national reports due in September 2007.[21] The COP-MOP adopted a format for first national reports at its third meeting,[22] and at its fourth meeting requested the Executive Secretary to suggest improvements to the reporting format for COP-MOP5.[23] According to the CPB website, 85 national reports have been received, indicating that a significant number of Parties have not yet submitted their first national reports that were due in 2007.[24]

21. In terms of the elaboration of additional rules, procedures and requirements under the Protocol, the COP-MOP has also, *inter alia*, adopted a decision containing more detailed requirements for the purpose of Article 18(2)(a).[25] Experience in implementation of this decision is due to be reviewed at COP-MOP 5 with a view to consideration of adoption of a further decision on Article 18(2)(a) at COP-MOP 6.[26] The COP-MOP will consider at COP-MOP 5 the possible adoption of rules and procedures and liability and redress pursuant to Article 27 of the CPB.[27]

22. The COP-MOP has also adopted numerous decisions at its four meetings to date which contain certain additional common understandings or guidance designed to guide Parties' implementation of the Protocol. Of particular interest for the assessment and review process, the COP-MOP has put in place a process for further consideration of the guidance on risk assessment in Annex III to the Protocol, establishing an Ad Hoc Technical Experts Group on Risk Assessment and Risk Management.[28] The Group's work will include, *inter alia*, consideration of the need for further guidance on specific types of risk assessment, for example in relation to particular types of LMOs, introduced traits and receiving environments. The Group's report is to be submitted to

[20] UNEP/CBD/BS/CC/6/3, 30 September 2009, para. 8.
[21] Decision BS-I/9. The experience of the first national reporting process is considered further below. According to Decision BS-I/9, para. 5, the frequency of national reporting is to be at four year intervals and, on this basis, second national reports would be due in 2011.
[22] Decision BS-III/14.
[23] Decision BS/IV/14. Note that the suggestions made in Part VI below, and the Annex, imply certain adjustments to the reporting format for second national reports in order to generate data for the effectiveness evaluation.
[24] According to the List of Parties on the CPB website, by September 2007 there were 141 Parties to the Protocol.
[25] Decision BS-III/10.
[26] *Ibid*, para . 7.
[27] UNEP/CBD/BS/GF-L&R/1/4, 27 February 2009, *Report of the Group of the Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety on the Work of its First Meeting.*
[28] The establishment of the Ad Hoc Technical Experts Group, and its terms of reference, are addressed in Decision BS-IV/11.

COP-MOP 5 and might be expected to contain material or recommendations pertinent to the evaluation of effectiveness under Article 35.

23. The COP-MOP has devoted significant attention to capacity-building for implementation of the Protocol. At COP-MOP, it adopted an Action Plan on capacity-building, and established a coordination mechanism for implementation of the Action Plan. It also adopted a set of indicators for monitoring implementation of the Action Plan. [29] The indicators were revised at COP-MOP 4.[30] The COP-MOP has regularly considered reports on the status of bilateral, regional and multilateral capacity-building activities. In addition, a number of coordination meetings have been held for governments and organisations implementing or funding biosafety-related activities, and the liaison group for capacity-building for biosafety has met six times. These activities have generated and made available a large amount of information about biosafety training and capacity-building opportunities. They have also provided an opportunity for developing country Parties to identify and notify their priority capacity needs. Nonetheless, it is widely recognised that a significant capacity gap remains.[31]

24. At its most recent meeting, the Liaison Group on Capacity-Building for Biosafety considered, *inter alia*, the capacity-building component of the proposed Strategic Plan for the CPB. In this context the group gave further consideration to indicators for monitoring the implementation of the Action Plan, and it was suggested that such indicators should be incorporated into the broader set of indicators for assessing implementation of the Protocol.[32]

III. Evaluation of effectiveness in other multilateral environmental agreements

25. The Cartagena Protocol on Biosafety is relatively unusual among MEAs in containing a specific provision, in Article 35, requiring periodic evaluations of effectiveness. This section briefly reviews approaches developed in some other MEAs that have undertaken some form of assessment and review. In a few cases such reviews have been conducted because, like the CPB, the MEA in question contains a specific provision requiring an evaluation of effectiveness or a similar form of assessment.[33] Such reviews are sometimes specifically focused on adaptation of the agreement to technical progress and evolving scientific knowledge. In other MEAs, mechanisms for evaluating effectiveness, in terms of progress towards specific goals, have been developed in the context of strategic planning processes, with a view to monitoring implementation of a

[29] Decision BS-I/5.
[30] Decision BS-IV/3.
[31] See generally, S. Johnston, C. Monagle, J. Green and R. Mackenzie, *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide*, UNU 2008.
[32] UNEP/CBD/BS/LG-CB/6/3, 19 October 2009, *Report of the Sixth Meeting of the Liaison Group on Capacity-Building for Biosafety*, para. 12.
[33] See for example, the discussion of the Basel and Stockholm Conventions, and the Montreal Protocol, below. Of ten agreements reviewed in 2001, Raustiala found that three (Basel Convention, Montreal Protocol and CITES) had some process for effectiveness review, and that, additionally, such a process was envisaged in the Ramsar Convention's Strategic Plan. His review did not include the Stockholm Convention. Raustiala, note 4 above, Appendix 2.

strategic plan and assessing progress towards goals and objectives established in the plan. In numerous other MEAs, the governing body, such as the conference of the parties, is accorded the general responsibility of keeping under review the implementation of the agreement without specific provisions on effectiveness evaluation.

Montreal Protocol on Substances that Deplete the Ozone Layer

26. The 1987 Montreal Protocol on Substances that Deplete the Ozone Layer provides, *inter alia*, for the reduction and phase-out of the production and consumption of certain specified ozone-depleting substances. Control measures for the covered substances are set out in the Protocol and are subject to regular adjustment and amendment in accordance with the procedures provided in the Protocol. Article 6 of the Montreal Protocol requires that beginning in 1990, and every four years thereafter, the Parties assess the control measures provided for on the basis of available scientific, environmental, technical and economic information. Article 6 also sets out the process by which such assessment and review shall take place, requiring the Parties to convene panels of experts in the relevant fields and to determine the composition and terms of reference of such panels. The panels report their conclusions to the Parties through the Ozone Secretariat.

27. On the basis of Article 6, the panel process was initiated in 1988 and four panels were established, addressing each of the areas identified in Article 6 of the Montreal Protocol. There now exist three panels: the Technology and Economic Assessment Panel; the Scientific Assessment Panel; and the Environmental Effects Assessment Panel. The panels have published periodic assessments to support the Article 6 review process. As a result of these reviews, the control measures under the Montreal Protocol have been tightened over time and have also been expanded to cover additional substances. The role of the panels focuses on the adequacy of existing control measures, including assessment of alternative substances and their economic implications.[34] In essence, the panels provide advice as to, *inter alia*, whether the existing control measures in the Protocol are adequate to address the problem of ozone depletion. In this sense, the Article 6 assessment and review process is squarely focused on the effectiveness of the Protocol in achieving its objective. The assessment and review process under the Montreal Protocol has been effective in facilitating and supporting the adaptation of the regime to evolving scientific technical and environmental knowledge.

Stockholm Convention on Persistent Organic Pollutants

28. The 2001 Convention on Persistent Organic Pollutants (POPs) aims to protect human health and the environment from POPs. It entered into force in May 2004. The Convention requires Parties, *inter alia*, to reduce or eliminate releases from the production and use of certain POPs. Article 16 provides for the evaluation of the effectiveness of the Convention commencing four years after entry into force and periodically thereafter at intervals to be decided by the

[34] http://ozone.unep.org/Assessment_Panels

Conference of the Parties (COP) to the POPs Convention. Article 16 requires the POPs COP to set in motion a process to facilitate this evaluation, by initiating arrangements to provide comparable monitoring data on the presence of certain chemicals and their regional and global environmental transport. The evaluation of effectiveness is to be conducted on the basis of available scientific, environmental, technical and economic information including: the monitoring information derived from the process initiated under Article 16; national reports submitted by Parties to the POPs Convention; and information provided pursuant to the POPs Convention's non-compliance procedure under Article 17.[35]

29. Although still at an early stage of evolution, the POPs Convention offers a developing model of organising a process of evaluation of effectiveness. The POPs Secretariat has noted that the purpose of effectiveness evaluation is to assess whether the implementation of the Convention has succeeded in meeting its objective.

30. For the first evaluation, the Secretariat sought to produce a baseline evaluation report, taking into account the available sources of information identified in Article 16 of the Convention. This included data from 44 national reports received by the Secretariat by the end of 2008.[36] The evaluation was based, *inter alia*, upon indicators identified for specific articles of the Convention, including the objective, and incorporated outcome indicators relating to the objective as well as process indicators to reflect measures or actions taken.[37] The Secretariat noted that the compilation of data was constrained by a number of factors, including the small number of national reports received, differences in the way Parties provided information, lack of specific information provided through the national reporting format, and the fact that not all Parties submitting reports had done so through the electronic reporting system.[38]

31. The POPs COP completed the first effectiveness evaluation at its fourth meeting in May 2009. It acknowledged that the Secretariat's document prepared for COP.4 comprised the first evaluation under Article 16, and that the information compiled on environmental monitoring and from the national reports submitted by Parties could be used as a baseline for comparative purposes in future evaluations. The COP noted that procedures for the evaluation stage of effectiveness evaluation had not yet been defined. It established an Ad Hoc Working Group on Effectiveness Evaluation, consisting of ten experts in programme evaluation nominated by Parties, two from each United Nations regions, to develop proposals for future evaluations, including how available information should be evaluated, data requirements and suggested changes to national reporting formats, and indicators. The COP set out a time frame for this

[35] N.B. The POPs Convention non-compliance has not yet been finalised. See COP decision SC-4/33: Procedures and mechanisms on compliance with the Stockholm Convention, UNEP/POPS/COP.4/38, 8 May 2009.

[36] *Ibid*, paras 7-9.
[37] *Ibid*, para 10.
[38] *Ibid*, para 92.

process and will consider the proposed procedures for future evaluations at its fifth meeting in 2011.[39] The Ad Hoc Working Group on Effectiveness Evaluation held its first meeting in November 2009.

Basel Convention on the Control of the Transboundary Movement of Hazardous Wastes and their Disposal

32. The 1989 Basel Convention regulates the transboundary movement of hazardous wastes. Article 15(7) of the Convention provides that the Conference of the Parties shall undertake, three years after entry into force of the Convention and at least every six years thereafter, an evaluation of its effectiveness. Specifically, Article 15(7) requires consideration of the need for a complete or partial ban on transboundary movements of hazardous wastes and other wastes in the light of latest scientific, environmental, technical and economic information. The Convention entered into force in May 1992. Raustiala notes that the first evaluation of effectiveness was prepared by a consultant in 1995 and focused on whether implementation of the Convention was on the 'right track',[40] it being considered premature at that stage to evaluate effectiveness in terms of the Convention's objectives.[41]

33. Consideration of effectiveness evaluation of the Basel Convention now seems to be incorporated with the Convention's evolving strategic framework.[42] The COP adopted a Strategic Plan for the period 2002-2010,[43] and a new strategic framework is currently under discussion for the post-2010 phase with a view to adoption at COP 10 in 2011. A recent draft discussion paper on the New Strategic Framework notes that '20 years after the adoption of the Convention . . . Parties continue to experience difficulties in evaluating its effectiveness. The principal source of such handicap emanates from the data collection and reporting shortcomings and the absence of agreed indicators to evaluate its effectiveness.'[44] The discussion paper recognises the need for an improved framework for assessing the effectiveness of the Convention and reviewing implementation. Within the proposed elements of the new draft strategic framework it proposes specific goals, objectives and actions, together with related indicators.[45]

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[39] COP Decision SC-4/32, UNEP/POPS/COP.4/38, 8 May 2009. To facilitate effectiveness evaluation, as required under Article 16, the POPs COP has also adopted a global monitoring plan for POPs. Decisions SC-2/13 and SC-3/19.

[40] K. Raustiala, *Reporting and Review Institutions in 10 Multilateral Environmental Agreements*, UNEP 2001, at 41.

[41] Raustiala reports, *ibid*, note 100, that the evaluation was made available in document UNEP/CHW.3/Inf.7. This document was not available for the purposes of the preparation of the present report and had not been reviewed.

[42] E-mail communication with the Secretariat of the Basel Convention.

[43] Decision VI/1, UNEP/CHW.6/40, 10 February 2003.

[44] *New Strategic Framework for the Implementation of the Basel Convention 2011-2020*, Draft 2 Discussion Paper, 10 November 2009, available at http://www.basel.int/stratplan/index.html. It should be emphasised that, as indicated in its title, the document is a discussion draft only and is open for comments by Parties and stakeholders. It forms an element of the consultation process towards development for the new 2011-2020 Strategic Framework.

[45] *Ibid*, p.10ff.

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

34. CITES does not contain a specific provision requiring effectiveness evaluation. Nonetheless, Article XI.3 requires the Conference of the Parties at its meetings to review the implementation of CITES and indicates in subparagraph (e) that it may 'where appropriate, make recommendations for improving the effectiveness of the Convention.'

35. In 1996, in accordance with a decision of the ninth meeting of the Conference of the Parties directed to the CITES Standing Committee, a study on improving the effectiveness of the Convention was conducted by a consultant.[46] The principal purposes of the review were to evaluate the extent to which the Convention had achieved its objectives and the progress made since CITES came into being and, most importantly, to identify deficiencies and requirements necessary to strengthen the Convention and help plan for the future.[47] Among the recommendations of the report was that a strategic plan should be prepared for CITES. Accordingly, a 'Strategic Vision through 2005' and an Action Plan were adopted at the 11th meeting of the CITES COP in 2000. The validity of this Strategic Vision was subsequently extended to 2007. The 2008-2013 Strategic Vision for 2008-13 sets out goals and objectives for CITES, and indicators of progress in relation to the various objectives were subsequently developed. [48] In line with the strategic objectives, the indicators are largely process-oriented focusing on the steps taken by Parties to implement the Convention and related CITES resolutions and decisions.

Ramsar Convention on Wetlands of International Importance

36. The 1971 Ramsar Convention requires Parties to promote conservation of wetlands in their territory listed as Wetlands of International Importance, and as far as possible to promote wise use of wetlands in their territory. The first strategic plan for the Ramsar Convention was adopted for the period 1997-2002, and a subsequent plan, covered 2003-2008. In 2008, the Conference of the Parties to the Ramsar Convention adopted a Strategic Plan for 2009-2015.[49]

37. In 2005, at Ramsar COP 9, a framework for the implementation of the 2003-08 Strategic Plan was adopted which provided, *inter alia*, a number of measures or indicators. In addition to the largely process-based indicators contained in that framework, the Ramsar Convention has also worked to develop ecological 'outcome-oriented' indicators for assessing the effectiveness of selected aspects

[46] CITES Doc. 10.20, *Evolution of the Convention: How to Improve the Effectiveness of the Convention, Comments from Parties and Organizations on the Study*, and Doc 10.21 *Evolution of the Convention: How to Improve the Effectiveness of the CITES, Consideration of the Recommendations arising from the Study.*
[47] CITES Resolution Conf. 14.2, *CITES Strategic Vision 2008-13*, Annex, General Introduction.
[48] CITES, *Indicators for Objectives contained in the CITES Strategic Vision: 2008-2013*, available at http://www.cites.org/eng/news/E-SV-indicators.pdf. See also CITES Doc. SC57 Doc. 9.
[49] Resolution X.1, *The Ramsar Strategic Plan 2009-2015*.

of the Convention's implementation in achieving the Convention's overall objective. [50]

Observations

38. It is apparent from the brief review above that there is a variety of experience with effectiveness evaluation and strategic plan reviews in other MEAs upon which future assessment and review processes under Article 35 CPB might draw. In several instances, however, such procedures and mechanisms remain at a relatively early stage of existence or are still under development. It is also important to keep in mind that the MEAs referred to above differ in significant respects from the CPB in terms of their objectives and the regulatory techniques that they employ.[51] Thus, the specific processes for evaluation of effectiveness or assessment of implementation may well not be directly transferable or appropriate to the CPB. Nonetheless it is considered instructive to consider whether elements of such approaches might yield useful insights into the CPB assessment and review process. As a general point, it is noteworthy that a number of other MEAs are grappling with the challenge of evaluating their effectiveness, often in the context of limited resources and national capacity of Parties, a lack of a prior common understanding of or framework for assessing effectiveness, and inadequate or incomplete existing sets of dedicated data upon which such evaluations can be based.[52]

IV. Strategic Plan of the Convention on Biological Diversity (CBD)

39. In addition to the processes surveyed above in relation to other MEAs, the Convention on Biological Diversity has adopted a Strategic Plan and developed a framework for reviewing progress towards the goals of that Plan, specifically the 2010 target. The Convention on Biological Diversity's Strategic Plan was adopted by the CBD Conference of the Parties in 2002,[53] and the Plan is to be updated at COP 10 in 2010. In 2004, the COP developed a framework of goals and targets, identifying provisional indicators in seven focal areas for evaluating status and trends of biodiversity and assessing progress towards the 2010 target.[54] The indicators were further considered and refined at COP 8.[55] The 2010 Biodiversity Indicator Partnership[56] is working on indicator development

[50] Resolution IX.1 Annex D, 2005, *Ecological 'outcome-oriented' indicators for assessing the implementation effectiveness of the Ramsar Convention*; Ramsar COP10 DOC. 23, 2008, *Further development of indicators of effectiveness of the implementation of the Convention*;

[51] For example, while a number of them, like the CPB, seek to control in some manner the transboundary movement of certain products in order to prevent adverse effects on the environment, some of them also explicitly provide for reducing or phasing out the production and/or consumption of certain substances. Measuring changes in, for example, the manufacture, import and export of persistent organic pollutants will inevitably pose different methodological challenges to measuring the impact of LMOs on the conservation and sustainable use of biological diversity.

[52] UNEP has also undertaken work on the effectiveness of MEAs, with particular focus on compliance and enforcement issues. See, for example, E. Mrema and C. Bruch, *Manual on Compliance with and Enforcement of Multilateral Environmental Agreements* (2006).

[53] CBD COP Decision VI/26.

[54] CBD COP Decision VII/30.

[55] CBD COP Decision VIII/15.

[56] www.twentyten.net.

and to generate information on biodiversity trends to assess progress as regards the 2010 target.

40. As attention focuses on the revision of the Strategic Plan for the post 2010 phase, further consideration is being given to the development and use of biodiversity indicators, and the question whether modified or new indicators may be required. An expert workshop in July 2009 recommended, *inter alia*, the modification and simplification of the current set of global indicators, and the development of some additional measures on threats to biodiversity.[57] Further thought might be given to whether it would be appropriate to address within this framework the consideration and possible development of indicators concerning any impact on biological diversity from LMOs, that might in future yield information useful to assessing the effectiveness of the CPB.

V. Evaluating the effectiveness of the Protocol under Article 35

Nature and scope of the assessment

41. As noted in the introductory section to this document, while Article 35 requires periodic evaluations of the effectiveness of the Protocol, it does not provide guidance as to how such evaluations should be conducted. Nor does it specify the nature or scope of the evaluation beyond indicating that it should encompass an assessment of the Protocol's procedures and annexes. The experience in other MEAs, and in the CBD, indicates that there are different ways in which such evaluations or measures of progress might be organised and conducted, and that the practice in this area is evolving.

42. In principle, an evaluation of the effectiveness of the Protocol should assess whether or to what extent the Protocol has achieved its objective. In relation to evaluation of effectiveness under the POPs Convention, the Stockholm Convention Secretariat noted that the review would 'assist the Parties to determine whether the Convention's provisions are sufficient to meet its objective or whether they need to be modified or additional measures adopted, or whether additional activities or projects should be undertaken to complement or improve the Convention's implementation to meet the objective.'[58] As noted by the Stockholm Convention Secretariat, evaluation of a programme or activity requires comparison of the situation before and after the action is taken.

43. In 2006, prior to the COP-MOP's first consideration of Article 35 at COP-MOP 3, the SCBD raised the question 'whether there has been enough experience gained by Parties that makes any evaluation of the effectiveness of the Protocol in the next few years appropriate and timely.'[59] The SCBD also noted the

[57] UNEP/WCMC/Post2010/0709/10, *UNEP WCMC/CBD International Expert Workshop on the 2010 Biodiversity Indicators and Post-2010 Indicator Development, 6-8 July 2009, Workshop Report*, available at http://www.cbd.int/doc/meetings/ind/emind-02/official/emind-02-0709-10-workshop-report-en.pdf.

[58] UNEP/POPS/COP.4/30, 5 February 2009, *Effectiveness Evaluation, Note by the Secretariat*, para. 2.

[59] UNEP/CBD/BS/COP-MOP/3/13, 9 January 2006, para 10. On the basis of reviews carried out at that time, the document reported that quite a number of Parties were then 'still at different levels of what

difficulties associated with pinpointing and attributing the specific impact of the Protocol in promoting or contributing to the conservation and sustainable use of biological diversity.[60]

44. The submissions of Parties and governments made prior to COP-MOP 4 revealed some differences of view as to the appropriate nature and scope of the assessment and review under Article 35.[61] While some seemed to indicate that the review should focus on implementation of the provisions of the Protocol, particularly those provisions that address advance informed agreement, others suggested a deeper focus on the extent to which the objective of the Protocol, set out in Article 1, had been achieved. A number recognised that the Protocol remained in its implementation phase, that there was still a low level of implementation, and thus it might be difficult or premature to evaluate fully its effectiveness.[62] Several referred to capacity impediments hampering implementation of the Protocol.

45. A number of Parties and Governments also made suggestions prior to COP-MOP 4 as to possible indicators and/or criteria for evaluating the effectiveness of the Protocol.[63] Many of these suggestions focused on implementation of biosafety frameworks at the national level in terms of the existence and implementation of a domestic regulatory framework, including risk assessment and risk management. A number mentioned capacity issues and identification of difficulties in implementation; others highlighted the role of the BCH and the number of submissions to the BCH. Some others suggested the development of specific indicators to measure the outcomes of the Protocol in terms of its objective.

46. As noted by the COP-MOP in Decision IV/15, the first national reports have shown that in many Parties the Protocol remains in an early stage of implementation. Indeed, in some respects, as the Protocol's Compliance Committee has noted, it remains difficult to ascertain with certainty the status of implementation of the Protocol at the domestic level since a number of Parties have yet to submit first national reports.[64]

47. It is difficult to conclude in 2009 that the situation as regards implementation of the Protocol has changed dramatically. Many of the national laws available on the BCH are still in the form of draft biosafety frameworks. Without further detailed Party-by-Party research, it is not possible to state with any certainty how many Parties have finalised, adopted and/or implemented their national biosafety frameworks since COP-MOP 4, or how many are in a position to

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could be considered as a preparatory phase towards the full implementation of the Protocol.' *Ibid*, para. 7.

[60] *Ibid*, paras 11-12.

[61] UNEP/CBD/BS/COP-MOP/4/INF/10, 3 April 2008, *Assessment and Review (Article 35): Compilation of Submissions of Views.*

[62] See the SCBD synthesis of the submissions in UNEP/CBD/BS/COP-MOP/4/14, 25 March 2008.

[63] UNEP/CBD/BS/COP-MOP/4/INF/10, 3 April 2008, *Assessment and Review (Article 35): Compilation of Submissions of Views*, at 19-25.

[64] The deadline for submission of the first regular national reports under Article 33 of the Protocol was 11 September 2007. According to the CPB website, 85 national reports have been received. There are 156 Parties to the Protocol. In September 2007, there were 141 Parties to the Protocol.

implement them in practice. While there have undoubtedly been developments in terms of domestic implementation, the dearth of detailed data in this respect, and of AIA decisions, on the BCH, and the continued expressions of concern about the capacity deficit at the national level, suggest that there has likely not been a significant improvement in the level of implementation of the Protocol since 2008.

48. If this conclusion is correct, it is suggested that the second evaluation of effectiveness should serve primarily to secure a global picture of the state of implementation of the Protocol and its impact to date in establishing a framework for information exchange, risk assessment and decision-making procedures in relation to the transboundary movement of LMOs. This could serve a baseline against which future improvements in implementation could be measured, and upon which might be built future evaluation of the effectiveness of the Protocol in achieving its objective.

49. It might be argued that such an approach risks duplicating the function of the existing system of monitoring implementation through the national reporting process. Indeed, it is suggested in Part VI below that national reports form the key data gathering mechanisms for the evaluation. However, in the view of the author, it seems premature to attempt to evaluate the Protocol's effectiveness in term of outcome i.e. its impact on conservation and sustainable use of biodiversity, taking into account risks to human health, when it seems evident that in many respects the regulatory procedures and mechanisms required under the Protocol have not yet been put into effect. In such circumstances, it may well not be possible reasonably to attribute to the Protocol impacts or the avoidance of impacts of LMOs on the conservation and sustainable use of biodiversity.[65]

50. The approach proposed does not disregard the fact that there may, and indeed should, be further improvements in the overall picture of implementation of the Protocol by 2010-2012, the period in which it is envisaged the second evaluation would take place. Notwithstanding the proposal that the second evaluation focuses primarily on assessing the status of implementation, some suggested options are put forward in the remainder of this paper for the development of a process to move towards more outcome-oriented evaluation in the future. Should it be considered timely and appropriate at COP-MOP 5, some of these elements could be integrated into the second evaluation process. In addition, some of the draft indicators proposed in the Annex go to the question whether existing guidance under the Protocol has thus far proved adequate (for example, in relation to risk assessment under Annex III).

VI. Possible elements of a methodology for the second evaluation of effectiveness

[65] This is not to imply that an evaluation of progress in relation to Article 1 could only be undertaken once every Party has realised the full implementation of its obligations under the Protocol, but rather that, as in any MEA, evaluation of implementation is always likely to be a component of effectiveness evaluation and, at this stage in the Protocol's evolution, seems to be the most significant component.

51. On the basis of the review above, this section sets out possible elements for the methodology for the second evaluation of effectiveness under Article 35. It considers: the timing of the assessment; its scope; a range of possible indicators that might be utilised as the basis for the evaluation; and mechanisms for gathering data for the assessment and for data analysis.

Timing

52. The first assessment under Article 35 was considered by the COP-MOP in 2008, five years after the Protocol entered into force, although, as noted in paragraph 2 above, it was considered that there did not then exist sufficient operational experience on which to base an effective assessment and review of the Protocol. In accordance with the terms of Article 35, future evaluations of effectiveness must be held at least every five years. Thus the next assessment should be conducted by 2013. Assuming that the current sequencing of COP-MOP meetings is maintained, COP-MOP 6 might be held in 2012 and COP-MOP 7 in 2014. This suggests that the second evaluation of effectiveness should be conducted by the COP-MOP at its sixth meeting in 2012.

53. As discussed in more detail below, it is suggested that data for the evaluation be collected primarily through the second national reports submitted by Parties to the Protocol. In Decision BS-I/9, the COP-MOP decided that national reports should be submitted by Parties every four years, and that they should be submitted 12 months before the meeting of the COP-MOP at which they will be considered. Since the first national reports were submitted in September 2007 for consideration by COP-MOP 4 in 2008, if the approach of Decision BS-I/9 is followed, the second national reports would be due in 2011 for consideration by COP-MOP 6 in 2012.

54. While this national reporting timeframe in principle corresponds with that suggested for the second evaluation of effectiveness, it should be acknowledged that it could impose difficulties on Parties in terms of timely submission of reports,[66] and on the Secretariat or such other entity that might be charged with compiling and analysing relevant evaluation data for consideration by the COP-MOP.

Scope

55. For the reasons discussed in Part V above, it is suggested that the second evaluation of effectiveness focus primarily on assessing the status of implementation of key provisions, procedures and mechanisms of the Protocol. In this way, the second evaluation should establish a set of baseline data against which future progress in the Protocol's implementation and effectiveness can be more reliably measured. Thus, in developing a preliminary list of draft indicators for consideration, an attempt has been made to focus on domestic implementation of certain core elements of the Protocol (see paragraph 70

[66] Document UNEP/CBD/BS/CC/5/2, the revised analysis of information contained in first national reports, prepared by the Executive Secretary notes that, taking into account the rate of timely submission of first national reports, Parties may wish to review the current reporting interval in Decision BS-I/9. (para. 98(o)).

below, and Annex). The second evaluation might also, it is suggested, provide a platform for the possible development of a core set of outcome indicators with which to begin to assess the effectiveness of the Protocol in achieving the objective set out in Article 1.

Data-gathering/sources of information

56. The methodology proposed for the second evaluation of effectiveness relies primarily on gathering information through the second national reports. This would require that the second national reporting format adopted by the COP-MOP incorporates indicators relevant to the assessment.

57. Reliance on national reports as the primary data source does entail, however, that the second evaluation of effectiveness will rely in large part upon the timely and complete submission of second national reports by Parties. On the basis of experience with the submission of first national reports, it should be acknowledged that difficulties in conducting the evaluation would be encountered if second national reports are submitted late or not at all.

58. Other sources of information are likely to include the BCH and other relevant biosafety databases, the reports of the Compliance Committee, the Capacity-Building Coordination Mechanism, and other international and regional organisations that address biosafety issues.

59. Data gathering and compilation might be undertaken by the SCBD.

Data analysis

60. There are a number of options that might be considered for the conduct of the data analysis phase of the evaluation. As noted in Part III above, some MEAs have relied upon their secretariat to compile and analyse data for the purposes of effectiveness evaluation and related exercises;[67] others have established expert panels[68] or ad hoc expert groups; and in some cases external consultants have been commissioned to conduct the evaluation. [69] Each of these options might be considered for the CPB evaluation. Another option might be to delegate the evaluation of effectiveness to the Compliance Committee which already reviews general issues of compliance at its meetings.

61. Subject to the availability of sufficient resources, the Secretariat might be charged with conducting the initial analysis of information gathered through the evaluation process. Nonetheless, it is submitted that it would be desirable at an early stage to establish a small ad hoc group of experts to participate in the evaluation, and, in due course, to begin to review and develop the initial set of indicators for the purposes of the third and subsequent evaluations of effectiveness.

[67] E.g., the first evaluation of effectiveness under the POPs Convention, paras. 28-31 above.
[68] E.g. Montreal Protocol on Ozone Depleting Substances, paras. 26-27 above.
[69] E.g. CITES 1996 report, paras. 34-35 above; first evaluation under the Basel Convention, paras. 32-33 above.

62. Given that the Compliance Committee also considers general issues of compliance at its meetings,[70] some consideration might be given to whether the Compliance Committee should be asked to assume responsibility for the conduct of the evaluation of effectiveness of the Protocol. The mandate of the Compliance Committee under Decision BS-I/7 indicates that, in addition to the specific functions laid down in that Decision, the Committee shall carry out any other functions as may be assigned to it by the COP-MOP. However, it might be argued that this may not be an appropriate role for the Committee, since it is also mandated to review individual cases of non-compliance. The effectiveness evaluation is not concerned with compliance by individual Parties, but rather with the overall implementation and effect of the CPB. Assuming that in the future individual cases of non-compliance might come before the Committee, it might be considered more appropriate to separate the functions of compliance review and effectiveness evaluation.

Integrating reporting, effectiveness evaluation and the strategic planning process in the CPB

63. It is envisaged that COP-MOP 5 may consider and adopt a Strategic Plan for the Protocol, incorporating strategic objectives and operational objectives, with specific indicators to monitor progress. If this is the case, consideration might usefully be given to the integration of future evaluations of effectiveness into any monitoring and review processes established for the Strategic Plan. Subject, of course, to the final content of the Strategic Plan, such an approach would appear *prima facie*, to satisfy the requirements of Article 35. Such an approach would also entail tailoring aspects of the content of national reporting requirements, as well as the timing of national reports, to the evaluation and monitoring process. In practical terms, it might offer an opportunity to achieve economies in data collection and analysis, and serve to lessen the reporting burden on parties.

Indicators

64. The Annex to this document sets out a draft core set of indicators for the second evaluation of effectiveness of the CPB. As noted previously, this is based on the approach that the second evaluation should focus primarily at this stage on evaluating overall domestic implementation of the Protocol's provisions. The purpose of setting out the draft indicators at this stage is to generate discussion as to whether this is an appropriate and useful approach.

65. A number of principles and assumptions have informed the development of the Annex, and it is worthwhile noting these here.

66. First, as noted in section V above, it is assumed that the effectiveness of the substantive provisions and annexes of the Protocol in achieving the desired outcome, i.e. the objective in Article 1, can be assessed only once the core procedures and mechanisms for implementation of the Protocol are in place. Hence the focus on national implementation at this stage.

[70] Decision BS-I/7, para. III.1(d).

67. Second, it is emphasised that the aim of the assessment and review process is not to evaluate the implementation of the Protocol by any individual Party or region, or to duplicate the work of the Compliance Committee in relation to possible instances of non-compliance. Rather the goal of the assessment and review is to ascertain the overall status of implementation, i.e. to what extent the Protocol's procedures have been put in place.

68. Third, the assessment and review is not intended to duplicate the review of national reports, that will, in any event, contain information on a broader range of issues and activities,.

69. Fourth, in drawing up the Annex, one principal consideration was the need to focus on a limited number of indicators in relation to which information should be readily available and measurable[71] through the reporting process or other available sources of information. This takes into account the need to draw on existing sources of information and not to overburden Parties with reporting requirements. That said, in relation to some of the proposed indicators some further thought may be required as to available sources of reliable data.

70. Fifth, in order to limit the number of indicators to a manageable number, the Annex focuses on certain core obligations contained in the Protocol, and thus at this stage excludes others. It is acknowledged that there may well be differences of view as to which elements of the Protocol might most usefully be subject to evaluation at this stage, and that the list contained in the Annex may need to be revised to take into account such views. The framework in the Annex focuses on the following aspects:

    i. The establishment of AIA procedures (or domestic regulatory frameworks consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction into the environment;

    ii. The operationalisation and functioning of AIA procedures (or domestic regulatory framework consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction into the environment;

    iii. The existence and operationalisation of procedures for risk assessment;

    iv. The existence and operationalisation of procedures for appropriate risk management measures and monitoring;

    v. The establishment and operationalisation of procedures for risk assessment and decision-making on transboundary movements of LMO-FFPs;

    vi. Procedures and capacities for identifying and addressing illegal transboundary movements of LMOs;

[71] The Liaison Group on Capacity-Building has noted at its most recent meeting that indicators for monitoring implementation of the capacity-building action plan should be revised to make them 'SMART', i.e. Specific, Measurable, Achievable, Relevant and Time-bound. UNEP/CBD/BS/LG-CB/6/3, 19 October 2009, para. 12(a).

vii. Procedures and capacities for avoiding and addressing unintentional transboundary movements of LMOs, including notification procedures and emergency measures;

viii. Appropriate implementation of CPB requirements on handling, transport, packaging and identification of LMOs and LMO-FFPs subject to intentional transboundary movement;

ix. Procedures and capacity for information-sharing through the BCH;

x. Procedures and measures for promoting public awareness.

71. A further assumption is that in order to achieve the desired objective of the Protocol, the geographic coverage of the Protocol should be as comprehensive as possible. If a significant number of states remain outside the Protocol, particularly those that are importers or exporters of LMOs and LMO-FFPs, this is likely to impact upon the potential for the Protocol's objective to be achieved. While this remains outside the control of Parties to the Protocol, nonetheless it is included in the Annex. In addition, the measure of coverage of the Protocol in the Annex would propose to seek to ascertain the proportion of transboundary movements of LMOs/LMO-FFPs that take place under the different procedures envisaged in the Protocol

VII. Conclusions and recommendations

72. The following conclusions and recommendations are offered as to the methodology for the second assessment and review:

a. The second evaluation should focus primarily on ascertaining and reviewing the status of implementation of core elements of the Protocol.

b. A set of indicators, based on the draft indicators contained in the Annex to this document, might inform the evaluation process for the purposes of the second evaluation of effectiveness.

c. Given the proposed focus of the evaluation, data for the evaluation should be gathered primarily through the CPB national reporting process. This may require some adjustments to the formats of national reports, and some consideration of the timing of second national reports.

d. The evaluation should also draw upon available information from other sources, including the BCH, the Capacity-Building Coordination Mechanism, and other relevant organisations.

e. The effectiveness evaluation process should be linked to, or integrated with, the process for the monitoring and review of the Protocol's Strategic Plan. This may impact upon the selection of indicators utilised. Such an

integrated approach might also incorporate the review of national reports and the monitoring of implementation of the capacity-building Action Plan.

f. In order to comply with the requirements of Article 35, the second evaluation of effectiveness should be completed at COP-MOP 6. COP-MOP 5 should therefore establish the basis for data gathering, including the determination of appropriate indicators and guidance on appropriate reporting formats, and allocate responsibilities for the review and analysis of data and the preparation of a report for COP-MOP 6.

g. The Secretariat might be charged with conducting the data gathering phase of the evaluation, and the initial compilation and analysis of data.

h. An ad hoc technical experts group might be established in order, before COP-MOP 6: (i) to advise on and/or participate in or conduct the review and analysis of data; and (ii) to advise on the modification of indicators and the development of further or alternative indicators as the basis for future evaluations of effectiveness under Article 35. Such indicators should include appropriate 'outcome-oriented' indicators to evaluate progress towards the objective of the Protocol. As an alternative to the establishment of an ad hoc technical experts group, part, or all, of these tasks might be mandated to the Compliance Committee.

i. The Compliance Committee, in its review of general issues of compliance, should have input into the effectiveness evaluation, and submit comments or recommendations thereon to COP-MOP 6.

j. The effectiveness evaluation process should incorporate forward-looking elements so as to consider whether there are new or emerging aspects of biosafety that might require attention under the Protocol.

k. Consideration should be given to the development of one or more CPB-relevant indicators in the wider context of the post-2010 Strategic Plan of the CBD, for example through the Biodiversity Indicators Partnership.

l. The CPB might usefully seek to share information and experience with other MEAS on effectiveness evaluation processes.

1. ANNEX

Possible indicators for second evaluation of effectiveness

*The draft indicators are presented here as a basis for discussion. Ideally, a smaller number of indicators would be used, but should be designed so as to yield information about the actual operation and functioning of national biosafety frameworks, not simply their existence on paper or in law. The precise wording of any of the measures proposed here might be modified in order to promote consistency, as far as appropriate, with other indicators generated for the Protocol (e.g. Strategic Plan; capacity-building Action Plan).

A. Coverage

1. Geographic coverage of the Protocol, and CPB coverage of transboundary movements of LMOs

    i. Number of Parties to the Protocol
    ii. Number of states that import or export LMOs that are Parties to the Protocol
    iii. Number of Parties that have designated national focal points
    iv. Number of Parties submitting timely national reports in relation to CPB
    v. Volume of LMOs for introduction into the environment and LMO-FFPs subject to transboundary movements
    vi. Percentage of LMOs and LMO-FFPs subject to transboundary movement that is subject to Protocol procedures

B. Domestic implementation of core procedures and annexes

2. AIA procedures (or domestic regulatory frameworks consistent with the Protocol), in accordance with CPB, are established for the transboundary movement of LMOs for intentional introduction into the environment

    i. Number of Parties that have finalised and adopted laws and all necessary regulations and administrative measures for operation of AIA procedure (or consistent domestic regulatory framework)
    ii. Number of Parties that export LMOs that have put in place laws and regulations consistent with the Protocol governing the export of LMOs
    iii. Number of Parties that have designated competent national authorities and notified them to the BCH
    iv. Number of Parties importing or exporting LMOs that do not have relevant laws and regulations in place governing transboundary movement
    v. Regional trends in establishment of AIA procedures

3. AIA procedures (or domestic regulatory framework consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction into the environment are operational and functioning

i. Number of Parties with domestic institutional and administrative (decision-making) arrangements in place to deal with AIA applications
ii. Number of Parties with budgetary allocation for operation of national biosafety framework
iii. Number of Parties with permanent staff in place to administer national biosafety frameworks (including AIA applications)
iv. Changes in number of permanent staff in place to administer national biosafety frameworks (including AIA applications)
v. Number of Parties that have processed AIA applications and reached decision on import (whether to accept, reject or subject to conditions)
vi. Number of AIA applications that have been processed to a decision on import (whether to accept, reject or subject to conditions)
vii. Number of Parties with biosafety laws, regulations or administrative measures that are still in draft form or that are not yet fully applied
viii. Regional trends in operation and functioning of AIA procedures

4. Procedures for decision-making in relation to transboundary movements of LMO-FFPs are established and operational

[Specific indicators in relation to LMO-FFPs could be integrated with those at points 2 and 3 above]

5. Risk assessment procedures for LMOs and LMO-FFPs are established and operational

i. Number of Parties with risk assessment guidelines in place for LMOs and LMO-FFPs
ii. Number of Parties that have conducted risk assessments as part of decision-making process on import of LMO or LMO-FFP
iii. Number of Parties with advisory committee or some other arrangements in place for conducting or reviewing risk assessment
iv. Number of Parties with domestic capacity to conduct risk assessment
v. Number of Parties reporting gaps or inadequacies in domestic risk assessment capacity
vi. Extent to which risk assessment guidelines in Annex III of the Protocol are reported by Parties to be adequate
vii. Extent to which a need for additional risk assessment guidelines is reported by Parties
viii. Regional trends in relation to risk assessment capacity

6. Procedures for the establishment of appropriate LMO and LMO-FFP risk management measures and monitoring are established and operational

i. Number of Parties that have authorised introductions of LMOs into the environment that have requirements and/or procedures in place and enforced to monitor the effects of those LMOs once released

ii. Number and nature of any unforeseen impacts of LMOs released into the environment
iii. Number of Parties with capacity to detect and identify presence of LMOs
iv. Regional trends in relation to risk management capacity
v. Extent to which a need for additional risk management guidelines is reported by Parties

7. Procedures for identifying and addressing illegal transboundary movements of LMOs and LMO-FFPs are in place and operational

i. Number of Parties with definition of illegal transboundary movement in domestic regulatory framework
ii. Number of illegal transboundary movements detected
iii. Number of Parties with capacity to detect illegal transboundary movements of LMOs (e.g. personnel, technical capacity)
iv. Number of Parties with measures in place to regulate transit of LMOs
v. Number of Parties with measures in place to regulate contained use of LMOs

8. Procedures for preventing, identifying and addressing unintentional transboundary movements of the LMOs and LMO-FFPs are established and operational, including notification procedures and emergency measures

i. Number of Parties having notified to BCH contact points regarding unintentional transboundary movement of LMOS in accordance with Article 17
ii. Number of Parties with mechanism in place for notifying potentially affected states of actual or potential unintentional transboundary movements of LMOs
iii. Number of instances of unintentional transboundary movements identified
iv. Nature and types of effects on biological diversity of any unintentional transboundary movements of LMOs

9. Appropriate requirements are established and implemented in relation to CPB requirements on handling, transport, packaging and identification of LMOs and LMO-FFPs subject to intentional transboundary movement

i. Number of Parties with requirements for handling, transport, packaging and identification of LMOs in place consistent with CPB Article 18 and relevant subsequent COP-MOP decisions for:
    i. Contained use
    ii. Intentional introduction into the environment
    iii. LMO-FFPs

10. Procedures for notification of required information to Biosafety Clearing House are established and operational

i. Number of Parties that have notified BCH of national focal points and competent national authorities
ii. Number of Parties that have allocated responsibilities for notification of information to BCH
iii. Number of Parties that have in place systems for biosafety data management
iv. Number of Parties that have notified up-to-date national laws, regulations and administrative measures through the BCH
v. Number of Parties notifying BCH of decisions on import of LMOs and LMO-FFPs, and time taken to notify BCH
vi. Number of Parties that have notified domestic decisions concerning approvals of LMO-FFPs, and time taken to notify BCH
vii. Number of Parties notifying risk assessments to BCH
viii. Number of Parties accessing BCH on a regular basis

11. Procedures and measures for promoting public awareness are being implemented
    i. Number of Parties implementing public awareness programmes or activities
    ii. Number of Parties providing for some level of public participation in decision-making processes on LMOs

C. International level procedures and mechanisms

12. BCH is operational and accessible
    i. Number of national laws, regulations etc available through BCH
    ii. Number of AIA/domestic decisions available through BCH
    iii. Number of risk assessments available through BCH
    iv. Number of Parties with reliable access to BCH
    v. Number of Parties reporting difficulties accessing or using the BCH
    vi. Extent to which information on BCH is reliable and up-to date

13. Capacity-building Action Plan being effectively implemented
    [Key indicators adopted in relation to the Action Plan on Capacity-building should be integrated here]

14. Compliance Committee is functioning
    i. Parties raise issues concerning their own compliance with Protocol obligations with Compliance Committee
    ii. Compliance Committee has decision-making rules of procedure in place

D. Impacts of transboundary movements of LMOs on biological diversity, taking into account risks to human health

[It is suggested that there might be some cross-reference here to wider work on biodiversity indicators being undertaken in relation to the CBD Strategic Plan; and that work might be initiated with a view to development of specific 'outcome-oriented' indicators relating to the Protocol objective. In addition,

the second evaluation might seek to gather and analyse data on reported instances of adverse effects of LMOs on the conservation and sustainable use of biological diversity, and on human health.]